(6)

No. 04-623

Supreme Court, U.S.
FILED
JAN 10 2005
OFFICE OF THE CLERK

IN THE

United States Supreme Court

JOHN ASHCROFT, Attorney General, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Petition For A Writ of Certiorari
To United States Court of Appeals for the Ninth Circuit

PATIENT-RESPONDENTS' BRIEF IN OPPOSITION

Nicholas W. van Aelstyn
Counsel of Record
Aaron S. Jacobs
Charles W. Burk
HELLER EHRMAN WHITE
& MCAULIFFE LLP
333 Bush Street
San Francisco, California 94104-2878
Telephone: 415-772-6000
Facsimile: 415-772-6268

Kathryn L. Tucker
COMPASSION & CHOICES
1201 Third Avenue, 40th Floor
Seattle, Washington 98101-3000
Telephone: 206-367-2134
Facsimile: 206-583-8500

Counsel for Patient-Respondents

QUESTION PRESENTED

Exercising its traditional police powers, Oregon enacted a law that allows physicians to prescribe and pharmacists to dispense Schedule II controlled substances to competent, terminally-ill adults who may use them under strictly regulated conditions to choose the time, place, and manner of their impending deaths. In enacting and amending the Controlled Substances Act (CSA), did Congress clearly authorize the Attorney General to determine that physicians and pharmacists acting in accordance with Oregon law have violated the CSA?

PARTIES TO THE PROCEEDING

Petitioners are John Ashcroft, Attorney General of the United States; Karen Tandy, Administrator of the Drug Enforcement Administration; Kenneth W. McGee, Assistant Special Agent-in-Charge of the Portland Office of the Drug Enforcement Administration; the United States of America; the United States Department of Justice; and the Drug Enforcement Administration.

Respondents are the State of Oregon, Peter A. Rasmussen, David Malcolm Hochhalter, John Doe #1 and Don W. James.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDING	ii
TABLE OF CONTENTS	iii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
STATEMENT OF JURISDICTION	1
STATUTES AND REGULATIONS INVOLVED	2
STATEMENT OF THE CASE	2
REASONS FOR DENYING THE PETITION	6
I. Introduction	6
II. Ashcroft's Interpretations of the CSA and Its Regulations Are Not Entitled to Deference.	7
A. Ashcroft's Interpretation of the CSA Is Not Entitled to Heightened Deference	8
1. The *Mead* and *Barnhart* factors require *Skidmore* respect, rather than *Chevron* deference	9
2. Ashcroft's interpretation is entitled to little respect under *Skidmore*	13

Page

B. Ashcroft's Interpretation of § 1306.04 Is Not Entitled to *Seminole Rock* Deference..... 15

III. Petitioners' Contention That the Directive Sets Forth the "Prevailing Views" of Physician-Assisted Dying Is Unsupported and Unsupportable..... 18

A. The Public, the Medical Community, and the States Are Divided on the Question of Physician-Assisted Dying..... 19

B. The Data Regarding Oregon's Experience with the ODWDA Demonstrate That Legal Physician-Assisted Dying Poses No Threat to Public Health..... 20

CONCLUSION..... 23

TABLE OF AUTHORITIES

Cases *Page*

Alaska Dept. of Environmental Conservation v. EPA, 540 U.S. 461, 124 S. Ct. 983 (2004)..... 10

Barnhart v. Walton, 535 U.S. 212 (2002)..... 9, 10

Bedford County Mem'l Hosp. v. HHS, 769 F.2d 1017 (4th Cir. 1985)..... 13

Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945)..... 15, 17

Caruso v. Blockbuster-Sony Music Entertainment Centre, 193 F.3d 730 (3d Cir. 1999)..... 16

Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)..... 8, 10

Christensen v. Harris County, 529 U.S. 576 (2000)..... 10

Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261 (1990)..... 3

Dubois v. U.S. Dep't of Agriculture, 102 F.3d 1273 (1st Cir. 1996)..... 12

Gardebring v. Jenkins, 485 U.S. 415 (1988)..... 15

Hall v. U.S. EPA, 273 F.3d 1146 (9th Cir. 2001)..... 14, 17

Humphreys v. DEA, 96 F.3d 658 (3d Cir. 1996)..... 13

Page

In re Sang-Su Lee,
277 F.3d 1338 (Fed. Cir. 2002) 12

James v. Von Zemenszky,
301 F.3d 1364 (Fed. Cir. 2002) 9

Lee v. Harcleroad,
522 U.S. 927 (1997)..... 3

Lee v. Oregon,
869 F. Supp. 1491 (D. Or. 1994)..... 2

Lee v. Oregon,
891 F. Supp. 1429 (D. Or. 1995)..... 2

Lee v. Oregon,
107 F.3d 1382 (9th Cir. 1997)..... 2

Martin v. Occupational Safety and Health Review Comm'n, 499 U.S. 144 (1991) 10

Menorah Med. Ctr. v. Heckler,
768 F.2d 292 (8th Cir. 1985)..... 13

Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Auto Insurance, 463 U.S. 29 (1983)..... 12

NLRB v. Brown,
380 U.S. 278 (1965)..... 15

Norfolk S. Railway v. Shanklin,
529 U.S. 344 (2000)..... 17

Olenhouse v. Commodity Credit Corp.,
42 F.3d 1560 (10th Cir. 1994)..... 13

Page

Oregon v. Ashcroft,
192 F. Supp. 2d 1077 (D. Or. 2002) 1, 5, 14, 18

Oregon v. Ashcroft,
368 F.3d 1118 (9th Cir. 2004) 1, 3, 4, 5

Pacific Coast Fed'n of Fishermen's Ass'n, Inc. v. Nat'l Marine Fisheries Serv.,
265 F.3d 1028 (9th Cir. 2001)..... 12

Puerto Rico Higher Educ. Assistance Corp. v. Riley, 10 F.3d 847 (D.C. Cir. 1993)..... 13

Sierra Club v. Martin,
168 F.3d 1 (11th Cir. 1999) 12

Skidmore v. Swift & Co.,
323 U.S. 134 (1944)..... 8, 14

Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers,
531 U.S. 159 (2001)..... 17

St. James Hospital v. Heckler,
760 F.2d 1460 (7th Cir. 1985)..... 13

Texas Office of Pub. Util. Counsel v. FCC,
265 F.3d 313 (5th Cir. 2001), *cert. denied*
535 U.S. 986 (April 15, 2002) 12

Thomas Jefferson Univ. v. Shalala,
512 U.S. 504 (1994)..... 15, 17

United States v. Mead Corp.,
533 U.S. 218 (2001)..... 9, 10

United States v. Oakland Cannabis Buyers' Coop,
532 U.S. 483 (2001)..... 14

Page

Washington v. Glucksberg,
521 U.S. 702 (1997) 3, 19

Statutes and Regulations

21 U.S.C. § 811(b) 11

36 Fed. Reg. 4948 (1971) 16

36 Fed. Reg. 7777 (1971) 16

36 Fed. Reg. 7799 (1971) 16

66 Fed. Reg. 56,607 (2001) 5

Or. Rev. Stat. § 127.865 20

S. Rep. No. 105-372, 105th Congress,
2d Session (1998) 4

S. Rep. No. 106-299, 106th Congress,
2d Session (2000) 4

Miscellaneous

Quill, Timothy E. MD; Cassel, Christine K. MD,
Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality, Annals of Internal Medicine,
Vol. 138(3), (2003) 19-20

Lunge, R.; Royle, M.; Slater, M.; Legislative Council, *Oregon's Death With Dignity Law and Euthanasia in the Netherlands: Factual Disputes* (2004), found at: http://www.leg.state.vt.us/reports/04Death/ Death_With_Dignity_Report.html 20, 22

Page

Fifth Annual Report on Oregon's Death with Dignity Act, Department of Human Services, Office of Disease Prevention and Epidemiology, March 6, 2003 21

Sixth Annual Report on Oregon's Death with Dignity Act, Department of Human Services Office of Disease Prevention and Epidemiology, March 10, 2004 21

IN THE

Supreme Court of the United States

No. 04-623

JOHN ASHCROFT, Attorney General, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Petition For A Writ of Certiorari
From the United States Court of Appeals for the Ninth Circuit

PATIENT-RESPONDENTS' BRIEF IN OPPOSITION

OPINIONS BELOW

The opinion of the Court of Appeals, Pet. App. 1a-63a, is reported at *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004). The opinion of the District Court, Pet. App. 64a-97a, is reported at *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002).

STATEMENT OF JURISDICTION

The judgment of the Court of Appeals was entered on May 26, 2004. A petition for rehearing was denied on August 11, 2004. Pet. App. 98a-99a. The petition for a writ

of certiorari was filed on November 9, 2004. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

Certain provisions of the Controlled Substances Act ("CSA") Pub. L. No. 91-513, Tit. II, 84 Stat. 1242 (21 U.S.C. §§ 801 *et seq.*), and a regulation promulgated thereunder, 21 C.F.R. § 1306.04, are set out in the Petitioner's Appendix at Pet. App. 149a-161a. Certain provisions of the Oregon Death with Dignity Act ("ODWDA") are set out in the Petitioner's Appendix at Pet. App. 162a-165a.

STATEMENT OF THE CASE

Patient-Respondents[1] adopt, for the purpose of this opposition to the petition for certiorari, Respondent State of Oregon's Statement of the Case.

Oregon voters approved the Oregon Death With Dignity Act ("ODWDA") on November 8, 1994. On November 23, 1994, opponents of the measure filed suit in federal court, alleging that the ODWDA violated their constitutional and statutory rights. *See Lee v. Oregon*, 869 F. Supp. 1491, 1493 (D. Or. 1994). The district court agreed and enjoined the ODWDA, *id.* at 1503 (granting preliminary injunction); *Lee v. Oregon*, 891 F. Supp. 1429 (D. Or. 1995) (granting permanent injunction), but in February of 1997 the Court of Appeals dismissed the complaint. *Lee v. Oregon*, 107 F.3d 1382, 1386 and 1392 (9th Cir. 1997).

[1] The "Patient-Respondents" are Respondents John Doe #1 and Don W. James.

Four months later, on June 27, 1997, this Court issued its decision in *Washington v. Glucksberg*, 521 U.S. 702 (1997), wherein the Court concluded:

> Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society.

Id. at 735. Concurring with the Court, Justice O'Connor explained:

> There is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure. . . . [T]he . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the "laboratory" of the States . . . in the first instance.

Id. at 737 (O'Connor, J., concurring) (quotation marks omitted) (quoting *Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 292 (1990) (O'Connor, J. concurring)). Shortly thereafter, this Court denied the *Lee* plaintiffs' petition for certiorari. *Lee v. Harcleroad*, 522 U.S. 927 (1997).

On November 4, 1997, after three years of litigation, the citizens of Oregon once again voted on the ODWDA, reaffirming their support for it by a margin of 60%. *See* Official Results State Measure 51 Nov. 4, 1997 State Wide Special Election at: http://www.sos.state.or.us/elections/nov497/other.info/m51abst.html. *See also Oregon v. Ashcroft*, 368 F.3d at 1122, Pet. App. at 6a-7a.

In response to requests by members of Congress in late 1997, including then-Senator Ashcroft, Attorney General Reno analyzed the question of whether practitioners acting in accordance with the ODWDA contravened the CSA. On June 5, 1998, Reno issued her interpretation of the CSA:

> The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

Letter from Reno to Hyde (June 5, 1998), Opp. App. at 50a. Reno explained that "[t]here is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice." *Id.*, Opp. App. at 52a.

Later that year the ODWDA's Congressional opponents, again including then-Senator Ashcroft, introduced the Lethal Drug Abuse Prevention Act of 1998 (the "LDAPA"), *see* S. Rep. No. 105-372, *Lethal Drug Abuse Prevention Act*, 105th Congress, 2d Session (1998), but it failed to reach the floor of the House or the Senate. *See* H.R. 4006 and S. 2151, 105th Congress (1998). They then introduced the Pain Relief Promotion Act of 1999 (the "PRPA"). *See* S. Rep. No. 106-299, *The Pain Relief Promotion Act*, 106th Congress, 2d Session (2000). The PRPA passed the House in 1999 and made it out of the Senate Judiciary Committee in 2000, but failed to reach a vote on the floor of the Senate. *See* H.R. 2260 and S. 1272, 106th Congress (1999). *See also Oregon v. Ashcroft*, 368 F.3d at 1123 n.4, Pet. App. at 7a-8a. Both the LDAPA and the

PRPA would have expanded the scope of the CSA to nullify the ODWDA. Both failed.

In November of 2000, the citizens of Missouri voted Senator Ashcroft out of office. President Bush then appointed him to be the Attorney General. Understandably concerned, Oregon's Attorney General wrote to Ashcroft, asking that Oregon be consulted in the event that the Department of Justice decided to reconsider the ODWDA. Letter from Hardy Myers, Oregon Attorney General, to John Ashcroft, United States Attorney General (February 2, 2001), Opp. App. at 55a. In response, Ashcroft stated that he "would be happy to include [Oregon's] views" if he ever revisited the matter. Letter from Lori Sharpe, Director and Advisor to the U.S. Attorney General, to Hardy Myers, Oregon Attorney General (April 17, 2001), Opp. App. at 58a.

However, on November 6, 2001, without even notifying Oregon, Ashcroft announced that he had reversed his predecessor's decision. Under his new interpretation of the CSA—even without passage of the LDAPA or the PRPA—prescribing controlled substances under the ODWDA is a violation of the CSA and will result in the revocation of a practitioner's license. *See* 66 Fed. Reg. 56,607 (November 9, 2001), Pet. App. at 100a. Respondents then filed this action. The District Court permanently enjoined the Ashcroft Directive, *Oregon v. Ashcroft*, 192 F. Supp. 2d 1077 (D. Or. 2002), Pet. App. at 64a, and the Court of Appeals affirmed, *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004), Pet. App. at 1a. This petition followed.

REASONS FOR DENYING THE PETITION

I. Introductio.

The petition seeks review of a decision that rests upon a straightforward and narrow statutory interpretation of the Controlled Substances Act. That decision presents no split among the circuits, and, despite petitioner's best efforts, no constitutional issues.[2] For these reasons alone review is not warranted.

In addition, the petition rests on several clearly incorrect contentions in an effort to call the decision into question. This is especially clear with respect to two contentions that lie at the heart of the petition:

> There can be no question, then, that the Attorney General's interpretive ruling [1] is consistent with the prevailing views regarding medical practice and [2] on that basis is, at the very least, reasonable and entitled to deference.

Pet. at 13. Both statements are clearly and demonstrably wrong, yet they constitute a critical basis of the petition. Indeed, petitioner demands deference from this Court at the outset, claiming *Chevron* deference and more for the Attorney General's interpretation of what constitutes a "legitimate medical practice." Pet. at 11-12.

While one may or may not agree with petitioner's views on physician-assisted dying—an issue that is deeply personal, highly sensitive and controversial—to contend that

[2] Petitioner's deeply flawed constitutional arguments are addressed in the brief of Respondent State of Oregon. Patient-Respondents therefore do not address this aspect of the petition and instead join the State of Oregon's Opposition.

they are nigh-universal and thus "the prevailing views" is simply wrong. Petitioner's bold assertions ignore the record in this case and the wider reality. There is, in fact, a robust debate across the nation about empowering dying patients to control the time and manner of death, and thereby avoid protracted and intolerable suffering, by obtaining medications from their physicians which they can self-administer to bring about a humane and peaceful death.

To assert that the Attorney General's (mis)characterization of the prevailing views of medical practice is entitled to great deference compounds the error. The relevant authorities make clear that Ashcroft's unilateral assertion of executive power overriding the intent of Congress, the will of the people of Oregon, the guidance of this Court in *Glucksberg*, and the wealth of data from both the medical community and the wider society, is not entitled to deference. That petitioner should make such strained arguments demonstrates his desperation to manufacture issues worthy of the attention of this Court. He has failed to do so on each of these core issues—that of the profound questions regarding dying and modern medicine that lie at the heart of this dispute, and that of the question of how much power is accorded to the executive alone in our federal system.

II. Ashcroft's Interpretations of the CSA and Its Regulations Are Not Entitled to Deference.

Petitioner contends that the Court of Appeals erred by failing to accord Ashcroft's Directive proper deference. Yet he provides no support for this bold assertion of executive power.

An agency's action is subject to separate standards of review depending upon whether it is interpreting a statute or its own regulation. Some actions implicate both, as here. Although Ashcroft stated that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)," Pet. App. at 102a, Section 1306.04 has nothing to do with suspending a health care provider's DEA registration. As such, Ashcroft turned to the CSA itself: "Such conduct by a physician . . . may render his registration . . . subject to possible suspension or revocation under 21 U.S.C. § 824(a)(4)." *Id.* (quotation marks omitted).

A. Ashcroft's Interpretation of the CSA Is not Entitled to Heightened Deference.

An agency's interpretation of a statute is generally entitled to one of two levels of deference—either the higher level of deference laid out by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), or the lower level of respect described in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Until petitioning this Court, Ashcroft did not claim *Chevron* deference; he expressly relied upon *Skidmore* below. *See, e.g.*, Br. for Appellants, 2002 WL 32157019 at 22 and 38-40 (Sept. 23, 2002). Notably, although petitioner demands *Chevron* deference in Section I.A.1 of the petition, he does not actually conduct a *Chevron* analysis or even argue for respect under *Skidmore*. *See* Pet. at 11-13. Rather, petitioner simply cites the standard-setting cases and assumes that the courts must accord the Directive deference. This is improper.

As a threshold matter, an agency's interpretation of a statute is entitled to *Chevron* deference only if it "appears

that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). If an agency passes the first test,[3] it still must establish the right to *Chevron* deference rather than *Skidmore* respect. This Court's recent decisions in *Barnhart v. Walton*, 535 U.S. 212 (2002), and *Mead* identified the factors used to select between these two standards. In particular, a court should consider: (1) the formality of interpretation; (2) the interstitial nature of the legal question; (3) the expertise of the agency; (4) the importance of the question to the administration of the statute; (5) the complexity of that administrative scheme; (6) the care of consideration; (7) the duration of consideration; and (8) the consistency of interpretation. *See Barnhart*, 535 U.S. at 222; *Mead*, 533 U.S. at 231-34; *see also James v. Von Zemenszky*, 301 F.3d 1364 (Fed. Cir. 2002) (discussing same). Petitioner neither engaged in an analysis of these factors nor even cited *Barnhart* or *Mead*. Their absence is not surprising, however, as each of the factors point towards *Skidmore's* lesser level of respect.

1. The *Mead* and *Barnhart* factors require *Skidmore* respect, rather than *Chevron* deference.

First, as *even petitioner admits*, the Ashcroft Directive is an "interpretive rule." *See* Pet. at 7 ("On November 9, 2001, the Attorney General published an interpretive rule . . . ."). *Chevron* deference is normally withheld from infor-

[3] Petitioner simply assumes that he has such power. State of Oregon's Opposition correctly explains why this is not the case. However, for the purposes of the following discussion, it may be assumed that he does possess such authority.

mal agency actions such as interpretive rulings. *Barnhart*, 535 U.S. at 222. As this Court explained, interpretive rules

> are not entitled to the same deference as norms that derive from the exercise of [an agency's] delegated lawmaking powers. Instead, interpretations contained in formats such as opinion letters are 'entitled to respect' under [the] decision in *Skidmore v. Swift & Co.*, but only to the extent that those interpretations have the power to persuade.

Christensen v. Harris County, 529 U.S. 576, 587 (2000) (quoting *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 157 (1991)) (citations and quotation marks omitted).[4] While discussing this provision, this Court noted in *Mead* that "the overwhelming number of our cases applying *Chevron* deference have reviewed the fruits of notice-and-comment rulemaking or formal adjudication." *Mead*, 533 U.S. at 230 n.12. Indeed, just last year this Court again refused to apply *Chevron* deference in a situation similar to the one here. *Alaska Dept. of Environmental Conservation v. EPA*, 540 U.S. 461; 124 S. Ct. 983, 1001 (2004) (holding that an EPA "internal guidance memoranda . . . does not qualify for the dispositive force described in *Chevron*") (citing *Christensen*, 529 U.S. at 587, and *Mead*, 533 U.S. at 234).

Second, the Ashcroft Directive was hardly an attempt to fill an interstitial gap. Unlike in *Barnhart*, the Ashcroft Directive does not plug a small hole in a regulatory scheme. *Barnhart*, 535 U.S. at 214-215, 223-224 (accepting the

[4] *See also Mead*, 533 U.S. at 232 ("[I]nterpretive rules . . . enjoy no *Chevron* status as a class."). *Chevron* itself explained that it applied only to "legislative regulations." *Chevron*, 467 U.S. at 844.

Social Security Administration's definitions of "inability" and "expected to last," notwithstanding the informal method used to arrive at those definitions).

Third, the Department of Justice lacks expertise in the medical field. In fact, in passing the CSA Congress specifically denied the Attorney General the power to make medical or scientific decisions with regards to drug control within the United States. Instead, Congress placed responsibility for making such decisions in the Department of Health and Human Service:

> The Attorney General shall, before initiating proceedings [to Schedule a drug], request from the Secretary [of Health and Human Services] a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled . . . . *The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.*

21 U.S.C. § 811(b), Opp. App. at 1a. Congress certainly did not intend to grant the Attorney General the power to decide what constitutes a legitimate medical practice if it withheld the authority to make medical or scientific decisions as to the scheduling of drugs.

Fourth, the ODWDA is of no importance to the administration of the CSA, which Congress intended to prevent drug trafficking and diversion. As the courts' exhaustive analyses below have made clear, the CSA was not intend-

ed to address the situations covered by the ODWDA. Pet. App. at 13a-14a & n.7; Pet. App. at 89a-92a.

Fifth, the CSA's administrative scheme has been made no more complex by protecting Oregon's physicians from prosecution when assisting in hastening humanely the deaths of competent, terminally ill patients in accordance with the ODWDA. Under the Ashcroft Directive it would be quite the opposite. DEA agents would be required to determine a doctor's intent, *post-facto*, whenever a patient dies after obtaining a prescription from that patient's doctor.

Sixth, the Attorney General did not consider the matter with care. The most probative evidence on the question of whether physician-assisted dying poses a threat to the public is the substantive data gathered pursuant to the ODWDA.[5] Yet this wealth of information was not cited once by either the OLC Memorandum or the Ashcroft Directive, and there are no findings or analyses anywhere in them that purport to show how this data relates to the alleged threat to the public interest. As this Court has noted, "an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem." *Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Auto Insurance*, 463 U.S. 29, 43 (1983).[6]

[5] *See* Section III.B, *infra*.

[6] Many courts have heeded this ruling in striking administrative rules based upon such a lack of honest consideration. *See, e.g., In re Sang-Su Lee*, 277 F.3d 1338, 1344-45 (Fed. Cir. 2002); *Texas Office of Pub. Util. Counsel v. FCC*, 265 F.3d 313, 323 (5th Cir. 2001) *cert. denied* 535 U.S. 986 (April 15, 2002); *Pacific Coast Fed'n of Fishermen's Ass'n, Inc. v. Nat'l Marine Fisheries Serv.*, 265 F.3d 1028, 1035-37 (9th Cir. 2001); *Sierra Club v. Martin*, 168 F.3d 1, 7 (11th Cir. 1999); *Dubois v. U.S. Dep't of Agriculture*, 102 F.3d 1273, 1285 (1st Cir. 1996); *Humphreys v. DEA*, 96 F.3d 658, 663 (3d Cir. 1996); *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1574-75 (10th Cir. 1994); *Puerto Rico Higher Educ. Assistance Corp. v. Riley*, 10 F.3d 847, 852 (D.C. Cir. 1993); *Bedford County Mem'l Hosp. v. HHS*, 769 F.2d 1017, 1022 (4th Cir. 1985); *Menorah Med. Ctr. v. Heckler*, 768 F.2d 292, 295-96 (8th Cir. 1985); *St. James Hospital v. Heckler*, 760 F.2d 1460, 1467-68 (7th Cir. 1985).

Seventh, it is impossible to tell how long the Attorney General considered his position, as the process occurred behind closed doors.

Eighth, the Directive is inconsistent with the Attorney General's prior, definitive position. Attorney General Reno previously "concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Letter from Janet Reno, United States Attorney General, Department of Justice, to Henry J. Hyde, Chairman, Committee on the Judiciary, House of Representatives (June 5, 1998), Opp. App. at 53a. Ashcroft's interpretation is a complete and improper reversal of this position.

Thus, all of the factors laid out in *Barnhart* and *Mead* indicate that the Directive is not entitled to *Chevron* deference. At most it warrants only *Skidmore* respect.

2. Ashcroft's interpretation is entitled to little respect under *Skidmore*.

Under *Skidmore*, an agency's interpretation of a statute may be entitled to respect, but the value of this respect "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors

which give it power to persuade . . . .". *Skidmore*, 323 U.S. at 140. Ashcroft's interpretation fails each of these criteria—which petitioner did not analyze—and, as such, was given the proper amount of respect by the court below.

Ashcroft did not thoroughly consider the matter. Although Ashcroft told Oregon's Attorney General that he "would be happy to include [Oregon's] views" if he ever revisited the ODWDA, he neither informed Oregon of the reconsideration nor included its views. *See* Letter from Sharpe to Myers (April 17, 2001), Opp. App. 58a. Neither did he consider any of the data gathered during the first four years of the ODWDA's existence. This is more edict than analysis, and does not merit *Skidmore* respect.

Ashcroft's legal reasoning lacks merit. The only legal precedent cited in the Directive is *United States v. Oakland Cannabis Buyers' Coop*, 532 U.S. 483 (2001). Pet. App. at 101a (citing same). Yet petitioner entirely abandoned this authority in the district court and mentioned it only in passing in the Court of Appeals. *See Oregon v. Ashcroft*, 192 F. Supp. 2d at 1092 n.20 (citation omitted), Pet. App. at 94a. This was not surprising as *Oakland Cannabis*' sole holding was that "medical necessity is not a defense to manufacturing and distributing marijuana." 532 U.S. at 494. The doctrine of medical necessity is not at issue here, nor are Schedule I substances, and thus *Oakland Cannabis* provides no support for the Directive.

Ashcroft's interpretation is inconsistent with previous interpretations. Lastly, as noted above, Ashcroft's interpretation conflicts with that of his predecessor. *See, e.g.*, *Hall v. U.S. EPA*, 273 F.3d 1146, 1156 (9th Cir. 2001)

(refusing to defer to an "interpretation advanced [by the EPA that] does not fit with prior interpretations").

Based upon the *Skidmore* factors, petitioner's interpretation of the CSA should receive no deference and little respect.

B. Ashcroft's Interpretation of § 1306.04 Is Not Entitled to *Seminole Rock* Deference.

Just as with its power to interpret statutes, an agency's power to interpret its regulations is neither unbounded nor unchecked. Courts "are not obliged to stand aside and rubberstamp their affirmance of administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *NLRB v. Brown*, 380 U.S. 278, 291 (1965). Instead, under *Seminole Rock*, such interpretations must be struck if "plainly erroneous or inconsistent with the regulation." *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945). Although petitioner cites certain cases from the *Seminole Rock* line of precedent, he again simply assumes deference without analysis. *See* Pet. at 11-12.

An agency must have some regulatory scheme in mind when it promulgates a rule and may not later depart from it without promulgating new rules. *See Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (noting that a court should not defer to an agency's interpretation where an "alternative reading is compelled by the regulation's plain language or by *other indications of the Secretary's intent at the time of the regulation's promulgation*") (quoting *Gardebring v. Jenkins*, 485 U.S. 415, 430 (1988))

(emphasis added).[7] Yet this is exactly what Ashcroft attempted to do by reinterpreting a thirty-year-old regulation to preempt the States' traditional role as the regulators of the medical profession within their borders.

In 1971, the Bureau of Narcotics and Dangerous Drugs published notice of the "Proposed Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970." *Purpose of Issue of Prescription*, 36 Fed. Reg. 4948 (1971), Opp. App. at 3a-4a. The proposed regulation included no official commentary and almost went unnoticed. The *only* public comment was summarized as follows: "The National Association of Retail Druggists objected to the responsibility placed upon a pharmacist under § [1306.04] to determine the legitimacy of a prescription. The language has been revised to require knowledge." *Comments and Objections to Part 306*, 36 Fed. Reg. 7777 (1971), Opp. App. at 5a-7a. The regulation was adopted substantially unchanged and has since remained untouched and largely unconstrued. *Purpose of Issue of Prescription*, 36 Fed. Reg. 7799 (1971), Opp. App. at 8a-9a.

Neither the regulation itself nor its lone public comment even hinted at Ashcroft's expansive interpretation. If it was intended as Ashcroft later interpreted it, the proposed regulation surely would have been accompanied by agency commentaries and would have prompted hundreds of public comments from medical groups and the states.

[7] *See, e.g., Caruso v. Blockbuster-Sony Music Entertainment Centre*, 193 F.3d 730, 736-37 (3d Cir. 1999) ("An agency is not allowed to change a legislative rule retroactively through the process of disingenuous interpretation of the rule to mean something other than its original meaning.") (citation omitted).

Moreover, it is rather unlikely that a shift of this magnitude in the constitutional role of the states would have been achieved by means of a single regulation routinely promulgated amidst many others. The obvious conclusion is that the Bureau did not intend to federalize the field of medicine. Ashcroft's interpretation of § 1306.04 is unreasonable. *Thomas Jefferson University*, 512 U.S. at 512.

Lastly, the Ashcroft Directive warrants no deference because it is contrary to Attorney General Reno's 1998 interpretation of the same regulation. *Norfolk S. Railway v. Shanklin*, 529 U.S. 344, 356 (2000) (striking agency's interpretation where it was inconsistent with prior construction). As this Court recently wrote in an analogous situation, "[a]lthough generally an agency's construction of its own regulations is entitled to substantial deference, no such deference is appropriate here. Not only is the [agency's] interpretation inconsistent with the text of [the regulation], but it also contradicts the agency's own previous construction . . . ." *Id.* (citation omitted).[8]

Given these faults, the Directive is "plainly erroneous [and] inconsistent with the regulation." *Seminole Rock*, 325 U.S. at 414. Ashcroft's interpretation is not entitled to *Seminole Rock* deference.

[8] *See also Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers*, 531 U.S. 159, 168 (2001) (noting that the agency interpretation before the Court reversed the agency's prior interpretation of the same rule, yet the agency had "put forward no persuasive evidence that the [agency] mistook Congress' intent" the first time); *Hall*, 273 F.3d at 1156.

III. Petitioners' Contention That the Directive Sets Forth the "Prevailing Views" of Physician-Assisted Dying Is Unsupported and Unsupportable.

Notwithstanding the broad support for physician-assisted dying demonstrated in the record below, petitioner continues to proclaim that the "prevailing views" of the practice are that it is illegitimate, Pet. at 12-13, and that those who support it are "far outside the mainstream." Pet. at 26-27.[9] This premise is unsupportable and reveals petitioner's disregard for the wide range of views on this serious issue. Petitioner's studied ignorance extends even to the most clearly relevant information regarding the practice of physician-assisted dying in the United States: the data reported on Oregon's six years of experience with physician-assisted dying under the strict regulation of the ODWDA.[10] While petitioner disregards the evidence, substantial support exists for the right of terminally-ill, competent adults to control the time, place, and manner of their impending deaths through the option of physician-assisted dying. There is simply no basis to support a blanket contention that a physician assisting a dying patient's exercise of this right by prescribing medications is acting outside the bounds of legitimate medical practice.

[9] *See also* Pet. at 6-7 (relying on Memorandum for the Attorney General from the Office of Legal Counsel, June 27, 2001 ("OLC Memo"), Pet. App. at 115a-117a; *Oregon v. Ashcroft*, 192 F. Supp. 2d. at 1083-84 (stating that the OLC Memo was written without any request for or consideration of Oregon statistics or input from Oregon representatives), Pet. App. at 75a-76a.

[10] The seventh year of implementation is just concluded and a report regarding the seventh year's data will issue in February 2005.

A. The Public, the Medical Community, and the States Are Divided on the Question of Physician-Assisted Dying.

Petitioner cites only selected portions of this Court's 1997 *Glucksberg* decision and the OLC Memo to support his contention that the "prevailing views" toward physician-assisted dying are that the practice is illegitimate. What is more, the OLC Memo itself relies almost exclusively upon incomplete and one-sided materials—namely, selected amici briefs submitted by opponents of physician-assisted dying in the *Glucksberg* case. Of course, there also were numerous amici briefs submitted in that case by those supportive of the practice. Petitioner likewise disregards the wide variety of amici that submitted briefs below in this case supporting the legitimacy of physician-assisted dying.

Petitioner disregards the support given by the citizens of Oregon that twice voted to adopt the ODWDA, choosing instead to characterize this entire polity as "far outside the mainstream." Petitioner also ignores the vast body of literature—including, most notably, everything that has happened since 1997—demonstrating that the debate concerning physician-assisted dying is vibrant and ongoing amongst the public, the health care community, and the States, as this Court predicted and encouraged. *Glucksberg*, 521 U.S. at 735. Recognizing the diversity of views within the medical community on the question, a significant number of medical associations have decided to embrace a position of "studied neutrality" on the question of legalizing physician-assisted dying.[11] Moreover, it is

[11] *See, e.g.*, Quill, Timothy E. MD; Cassel, Christine K. MD, *Professional Organizations' Position Statements on Physician-Assisted Suicide: A Case for Studied Neutrality*, Annals of Internal Medicine, Vol.

increasingly an informed debate: as more data emerges from the State of Oregon, speculation gives way to empirical evidence about the relative risks and benefits of the practice.[12]

B. The Data Regarding Oregon's Experience with the ODWDA Demonstrate That Legal Physician-Assisted Dying Poses No Threat to Public Health.

Petitioner's studied ignorance extends beyond the general to the specific: he ignores the actual data collected during Oregon's six years of experience with legal physician-assisted dying. Ashcroft's Directive simply assumed that the ODWDA harmed Oregonians without examining the facts. The Oregon data is not mentioned even once in the Directive, the OLC Memo, petitioner's briefs below, nor even in the petition for certiorari.

As required by the ODWDA, Oregon's experience with legal physician-assisted dying has been extensively documented and studied. Or. Rev. Stat. § 127.865, Opp. App. at 10a. To date, the Oregon Health Division and/or the Oregon Department of Human Service Office of Disease Prevention and Epidemiology have issued six annual reports that present and evaluate the State's experience with the

138(3) (2003), pp. 208-211 (attaching appendix listing Medical Organizations with Neutral Stance on Physician-Assisted Suicide).

[12] *See, e.g.*, Lunge, R.; Royle, M.; Slater, M.; Legislative Council, *Oregon's Death With Dignity Law and Euthanasia in the Netherlands: Factual Disputes* (2004), found at: http://www.leg.state.vt.us/reports/04Death/ Death_With_Dignity_Report.html (2004 report to the Vermont legislature by the Vermont Legislative Council).

ODWDA.[13] These reports present the only reliable data regarding the experience of legal, regulated physician-assisted dying in America.

The data demonstrate that physician-assisted dying does not pose a threat to public health and safety. Physician-assisted dying is not being forced upon those who are uneducated, uninsured or otherwise disadvantaged, a threat that opponents of the ODWDA speculated would materialize.

Further, the data demonstrate that use of physician-assisted dying is quite limited. During the six years in which the practice has been legal in Oregon, a total of 171 Oregonians have chosen this option. Sixth Annual Report at 19, Opp. App. at 35a. The number of terminally-ill adults choosing this option in 2003 represents only one-seventh of one percent—*i.e.*, 0.14 percent—of Oregonians who died that year. *Id.* at 5, Opp. App. at 20a.

Indeed, rather than posing a risk to patients or the medical profession, the ODWDA has led to significant improvements in the care of the dying in Oregon. *Id.* at 16, Opp. App. at 32a. In the course of considering passage of a similar law, the State of Vermont reviewed the Oregon experience and concluded that "it is [quite] apparent from credible sources in and out of Oregon that the Death with Dignity Act has not had an adverse impact on end-of-life care and in all probability has enhanced the other options."

[13] *See, e.g.*, Sixth Annual Report on Oregon's Death with Dignity Act, Department of Human Services Office of Disease Prevention and Epidemiology, March 10, 2004 ("Sixth Annual Report"), Opp. App. at 11a; Fifth Annual Report on Oregon's Death with Dignity Act, Department of Human Services, Office of Disease Prevention and Epidemiology, March 6, 2003, Opp. App. at 44a.

R. Lunge *et al.*, *Oregon's Death With Dignity Law and Euthanasia in the Netherlands: Factual Disputes*, at p. 26.

In sum, the available data demonstrate that physician-assisted dying, far from posing any hazard to patients or the practice of medicine, has galvanized improvements in end-of-life care, benefiting all terminally-ill Oregonians. Petitioner ignores this data just as he ignored it when issuing the Directive. Rather than face the facts of this data and the fact that many within the medical community and the wider society hold views contrary to his own, petitioner asserts that the courts must defer to his blinkered view of the "prevailing views." Such studied ignorance warrants no deference by this Court, and thus this case does not warrant review.

CONCLUSION

The petition seeks to manufacture issues worthy of this Court's review where there are none. In doing so, it mischaracterizes the state of the debate on the profound issue of physician-assisted dying, and compounds this error by contending that the courts must defer to the Attorney General's narrow views on the subject. The first defies the facts and the second the law. The decision below is a well-reasoned and narrow construction of the CSA, and is not contrary to the decision of any other circuit. The petition for a writ of certiorari should be denied.

Respectfully submitted,

NICHOLAS W. van AELSTYN
Counsel of Record
AARON S. JACOBS
CHARLES W. BURK
HELLER EHRMAN WHITE & MCAULIFFE LLP
333 Bush Street
San Francisco, CA 94104-2878
Telephone: (415) 772-6000
Facsimile: (415) 772-6268

Counsel for Patient-Respondents

KATHRYN L. TUCKER
COMPASSION & CHOICES
1201 3rd Avenue, 40th Floor
Seattle, WA 98101-3000
Telephone: (206) 367-2134
Facsimile: (206) 583-8500

Counsel for Patient-Respondents

APPENDIX

APPENDICES

	Page
21 U.S.C. § 811(b)	1a
§ 306.04 – Purpose of issue of Prescription, 36 Fed. Reg. 4948 (March 13, 1971)	3a
Comments and Objections to Part 306, 36 Fed. Reg. 7777 (April 24, 1971).....	5a
§ 306.04 –Purpose of Issue of Prescription, 36 Fed. Reg. 7799 (April 24, 1971).....	8a
The Oregon Death With Dignity Act – Or. Rev. Stat. § 127.865.....	10a
Oregon Department of Human Services, *Sixth Annual Report on Oregon's Death with Dignity Act*, March 10, 2004; and March 16, 2004 cover letter from Hilary E. Ware submitting same to Court of Appeal for consideration	11a
K. Hedberg, M.D., M.P.H.; D. Hopkins, M.S.; M. Kohn, M.D., M.P.H.; *Five Years of Legal Physician-Assisted Suicide in Oregon*, New England Journal of Medicine, Volume 348:961-964, March 6, 2003; and March 19, 2003 cover letter from Hilary E. Ware submitting same to Court of Appeal for consideration	44a
June 5, 1998 letter from U.S. Attorney General Janet Reno to Henry J. Hyde, Chairman of Committee on the Judiciary, U.S. House of Representatives.....	50a

February 2, 2001 letter from Hardy Myers, Oregon Attorney General, to John Ashcroft, Attorney General of the United States 55a

April 17, 2001 letter from Lori Sharpe, Director and Advisor to the U.S. Attorney General, to Hardy Myers, Oregon Attorney General 58a

21 U.S.C. § 811(b)

§ 811. Authority and criteria for classification of substances

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the

drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

FEDERAL REGISTER

VOLUME 36 • NUMBER 50

Saturday, March 13, 1971 • Washington, D.C.

PART II

Department of Justice

Bureau of Narcotics and Dangerous Drugs

•

Proposed Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970

PART 306—PRESCRIPTIONS

General Information

§ 306.04 Purpose of issue of prescription.

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person filling such a prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

FEDERAL REGISTER

VOLUME 36 • NUMBER 80

Saturday, April 24, 1971 • Washington, D.C.

PART II

Department of Justice

Bureau of Narcotics and Dangerous Drugs

•

Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970

COMMENTS AND OBJECTIONS TO PART 306

1. The National Association of Retail Druggists objected to the responsibility placed upon a pharmacist under § 306.04 to determine the legitimacy of a prescription. The language has been revised to require knowledge.

2. Several pharmacy groups protested the requirement under § 306.11(c)(4) that, if a doctor fails to provide an authorization for emergency order as required, the pharmacist must so report to the Bureau or be liable for dispensing a substance in schedule II without a written prescription. The Director considered the problems and concluded that only this mechanism assures information to the Bureau about doctors who refuse to comply with the Act.

3. The American Pharmaceutical Association and the National Association of Chain Drug Stores suggested that, in the case of a partial filling of a schedule II substance, the pharmacist notify the doctor only when the remainder cannot be filled, in order for the doctor to issue a new prescription. The language was revised accordingly.

4. All retail druggist associations urged revision in the labeling requirements for prescriptions set forth in §§ 306.14 and 306.23. In response, the Director has had the requirements of inclusion of the patient's address and the doctor's registration number deleted.

5. In response to a comment from the National Association of Retail Druggists, a definition of prescription was added which covers all orders for medication except hospital orders (i.e., orders for medication to be administered immediately and cannot be removed from the hospital either by an out-patient or by an in-patient being dis-

charged). Sections 306.11, 306.21, and 306.31 were revised to indicate that institutional practitioners (e.g., hospitals) can only dispense by prescription or hospital order.

6. Several questions were asked about the status of paregoric. This is a schedule III substance which is not now a prescription drug under the Food, Drug and Cosmetic Act and therefore not subject to the prescription requirements of the Controlled Substances Act. Until such time as it becomes a prescription drug, the Director has determined to treat it in the same manner as a schedule V substance. Section 306.32 has been revised accordingly.

FEDERAL REGISTER

VOLUME 36 • NUMBER 80

Saturday, April 24, 1971 • Washington, D.C.

PART II

Department of Justice

Bureau of Narcotics and Dangerous Drugs

•

Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970

§ 306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs, in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

The Oregon Death With Dignity Act
Or. Rev. Stat. § 127.865

Reporting requirements.

(1)(a) The Department of Human Services shall annually review a sample of records maintained pursuant to ORS 127.800 to 127.897.

(b) The department shall require any health care provider upon dispensing medication pursuant to ORS 127.800 to 127.897 to file a copy of the dispensing record with the department.

(2) The department shall make rules to facilitate the collection of information regarding compliance with ORS 127.800 to 127.897. Except as otherwise required by law, the information collected shall not be a public record and may not be made available for inspection by the public.

(3) The department shall generate and make available to the public an annual statistical report of information collected under subsection (2) of this section. [1995 c.3 § 3.11; 1999 c.423 §9; 2001 c.104 § 40]

[LETTERHEAD]

HELLEREHRMAN
ATTORNEYS

March 16, 2004

Hilary E. Ware
hware@hewm.com
Direct (415) 772-6459
Main (415) 772-6000
Fax (415) 772-6268

Via Hand Delivery

[Stamp]
RECEIVED
OFFICE OF THE CLERK
U.S. COURT OF APPEALS
PUBLIC INFORMATION UNIT
04 MAR 16 PM 12:03
FILED _____
DOCKETED _____
DATE INITIAL

Office of the Clerk
United States Court of Appeals for the
Ninth Circuit
P.O. Box 193939
San Francisco, CA 94119-3939

Re: *State of Oregon et al., v. Ashcroft*
Case No. 02-35587

Dear Sir or Madam:

Pursuant to Rule 28(j) of the Federal Rules of Appellate Procedure, the Patient Plaintiffs-Appellees in the above-mentioned case wish to bring to the Court's attention a significant supplemental authority that has recently been released. On March 10, 2004, the Oregon Department of

Human Services released the "Sixth Annual Report on Oregon's Death with Dignity Act," an examination of data from the sixth year of the Oregon Death With Dignity Act ("ODWDA"). The Patient Plaintiffs-Appellees cited and discussed the data contained in the reports from the first four years of the ODWDA in their Brief at pages 13-14 and 37 n. 105, and submitted the report from the fifth year by a similar request on March 19, 2003. This report should also be considered in that context.

A copy of this report is enclosed with this request, and is also available at http://www.dhs.state.or.us/publichealth/chs/pas/pas.cfm. Thank you for your consideration of this request.

Very truly yours,

/s/ HILARY E. WARE
Hilary E. Ware

cc: All Counsel of Record
Enclosures

[Letterhead bottom:]

Heller Ehrman White & McAuliffe LLP
333 Bush Street
San Francisco, CA 94104-2878
www.hewm.com

San Francisco Silicon Valley Los Angeles San Diego
Seattle Portland Anchorage New York Washington D.C.
Madison, WI Hong Kong Singapore
Affiliated Offices: Milan Paris Rome

PROOF OF SERVICE BY FACSIMILE AND U.S. MAIL

I, Gary Padilla, declare as follows:

I am employed with the law firm of HELLER, EHRMAN, WHITE & MCAULIFFE, whose address is 333 Bush Street, San Francisco, California 94104-2878. I am readily familiar with the business practices of this office for collection and processing of correspondence for mailing with the United States Postal Service and for the transmission of documents by facsimile. I am over the age of eighteen years and not a party to this action.

On March 16, 2004, I served the following document:

LETTER TO COURT CLERK RE SUPPLEMENTAL AUTHORITY PURSUANT TO RULE 28(j) OF THE FEDERAL RULES OF APPELLATE PROCEDURE

on the below party(s) in this action by transmitting by facsimile machine and by placing true copies thereof in sealed envelopes, addressed as shown, for collection and mailing pursuant to the ordinary business practice of this office which is that correspondence for mailing is collected and deposited with the United States Postal Service on the same day in the ordinary course of business:

Gregory Katsas, Esq.
Mark B. Stern, Esq.
Jonathan H. Levy, Esq.
U.S. Dept. of Justice –
Civil Division
Appellate Staff
Room 9541 PHB
601 D Street, N.W.
Washington, D.C. 20530-0001

Robert B. Rocklin
Assistant Attorney General
Appellate Division
Oregon Department of Justice
1162 Court Street NE
Salem, OR 97301-4096

Eli D. Stutsman
621 SW Morrison, 13th Floor
Portland, OR 97205

Stephen K. Bushong
Trial Division
Oregon Department of Justice
1162 Court Street, NE
Salem, OR 97301-4096

Kathryn Tucker
Compassion in Dying Federation
1201 3rd Avenue, 40th Floor
Seattle, WA 98101-3000

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed at San Francisco, California, on March 16, 2004.

/s/ GARY PADILLA
Gary Padilla

Sixth Annual Report on
Oregon's Death with
Dignity Act

[Stamp]
STATE OF OREGON
1859

Department of Human Services
Office of Disease Prevention and Epidemiology
March 10, 2004

[Logo]
DHS
Oregon Department
of Human Services

Sixth Annual Report on Oregon's Death with Dignity Act

For more information contact:
Darcy Niemeyer
Department of Human Services, Health Services
Office of Disease Prevention and Epidemiology
800 N.E. Oregon Street, Suite 730
Portland, OR 97232
E-mail: darcy.niemeyer@state.or.us
Phone: 503-731-4023
Fax: 503-731-4082
http://www.dhs.state.or.us/publichealth/chs/pas/pas.cfm

Contributing Editor: Richard Leman, MD
Date Analysis: David Hopkins, MS

Acknowledgements

This assessment was conducted as part of the required surveillance and public health practice activities of the Department of Human Services and was supported by Department funds.

Table of Contents

Summary 4
Introduction 6
History 6
Requirements 7
Methods
The Reporting System 9
Data Analyses 10
Results 11
Patient Characteristics 12
Physician Characteristics 13
Lethal Medication 13
Complications 14
End of Life Concerns 14
Comments 15
References 17
Tables
Table 1 19
Table 2 21
Table 3 22
Table 4 23

SUMMARY

Physician-assisted suicide (PAS) has been legal in Oregon since November 1997, when Oregon voters approved the Death with Dignity Act (DWDA) for the second time (see *History*, page 6). The Department of Human Services (DHS) is legally required to collect information regarding compliance with the Act and make the information available on a yearly basis. In this sixth annual report, we characterize the 42 Oregonians who, in 2003, ingested medications prescribed under provisions of the Act, and look at whether the numbers and characteristics of these patients differ from those who used PAS in prior years. Patients choosing PAS were identified through mandated physician and pharmacy reporting. Our information comes from these reports, physician interviews and death certificates. We also compare the demographic characteristics of patients participating during 1998-2003 with other Oregonians who died of the same underlying causes.

In 2003, 42 physicians wrote a total of 67 prescriptions of lethal doses of medication. The number of prescriptions written increased in each of the previous years: 58 prescriptions were written in 2002, 44 in 2001, 39 in 2000, 33 in 1999, and 24 in 1998. Thirty-nine of the 2003 prescription recipients died after ingesting the medication. Of the 28 persons who did not ingest the prescribed medication, 18 died from their illnesses, and 10 were alive on December 31, 2003. In addition, two patients who received prescriptions during 2002 and another who received a prescription in 2001 died in 2003 after ingesting their medication for a total of 42 PAS deaths during 2003.

There were four more patients who used PAS in 2003 than in 2002, and the number of patients ingesting lethal

medication has increased over the six years since legalization. In 2003, 42 patients died from PAS, compared to 38 in 2002, 21 in 2001, 27 in 2000, 27 in 1999, and 16 in 1998 [1-5]. The 42 patients who ingested lethal medications in 2003 represent an estimated 14/10,000 total deaths, compared with 12.2 in 2002, 7.0 in 2001, 9.1 in 2000, 9.2 in 1999, and 5.5 in 1998. Compared to all Oregon decedents in 2003, PAS participants were more likely to have malignant neoplasms (83%), to be younger (median age 73 years), and to have more formal education (48% had at least a baccalaureate degree).

During the past six years, the 171 patients who took lethal medications differed in several ways from the 53,544 Oregonians dying from the same underlying diseases. Rates of participation in PAS decreased with age, but were higher among those who were divorced or never married, those with more years of education, and those with amyotrophic lateral sclerosis, HIV/AIDS, or malignant neoplasms (see *Patient Characteristics*, page 12).

Physicians indicated that patient requests for lethal medications stemmed from multiple concerns related to autonomy and control at the end of life. The three most commonly mentioned end-of-life concerns during 2003 were: loss of autonomy, a decreasing ability to participate in activities that made life enjoyable, and a loss of dignity (see *End of Life Concerns*, page 15).

During 2003, 37 patients (88%) used pentobarbital as their lethal medication, four patients (10%) used secobarbital, and one (2%) used secobarbital/amobarbital (Tuinal). (see *Lethal Medication*, page 14).

During 2003, complications were reported for three patients. All involved regurgitation and none involved seizures (see *Complications*, page 14). One-half of patients

became unconscious within four minutes of ingestion of the lethal medication and died within 20 minutes. The range of time from ingestion to death was five minutes to 48 hours. Emergency medical services were called by one patient's family to pronounce death; neither resuscitation nor transport was requested.

Although the number of Oregonians ingesting legally prescribed lethal medications has increased, the overall number of terminally ill patients ingesting lethal medication has remained small, with about 1/7 of one percent of Oregonians dying by physician-assisted suicide.

INTRODUCTION

This sixth annual report reviews the monitoring and data collection system that was implemented under Oregon's Death with Dignity Act (DWDA), which legalizes physician-assisted suicide (PAS) for terminally ill Oregon residents. This report summarizes the information collected on patients and physicians who participated in the Act in its sixth year of implementation (January 1, 2003 to December 31, 2003) and examines trends over the six years since legalization. Using physician reports, interviews, and death certificates, we address the following questions: Is the number of residents using legal PAS in Oregon increasing? Do patients who participated in 2003 resemble patients using PAS in previous years and other Oregonians dying from similar diseases? Have any changes occurred in the PAS process during the past six years?

History

The Oregon Death with Dignity Act was a citizen's initiative first passed by Oregon voters in November 1994 with 51% in favor. Implementation was delayed by a legal injunction, but after proceedings that included a petition denied by the United States Supreme Court, the Ninth Circuit Court of Appeals lifted the injunction on October 27, 1997. In November 1997, a measure asking Oregon voters to repeal the Death with Dignity Act was placed on the general election ballot (Measure 51, authorized by Oregon House Bill 2954). Voters rejected this measure by a margin of 60% to 40%, retaining the Death with Dignity Act. After voters reaffirmed the DWDA in 1997, Oregon became the only state allowing legal physician-assisted suicide [6].

Although physician-assisted suicide has been legal in Oregon for six years, it remains highly controversial. On November 6, 2001, US Attorney General John Ashcroft issued a new interpretation of the Controlled Substances Act, which would prohibit doctors from prescribing controlled substances for use in physician-assisted suicide. To date, all the medications prescribed under the Act have been barbiturates, which are controlled substances and therefore, would be prohibited by this ruling for use in PAS. In response to a lawsuit filed by the State of Oregon, on November 20, 2001, a US district court issued a temporary restraining order against Ashcroft's ruling pending a new hearing within 5 months. On April 17, 2002, U.S. District Court Judge Robert Jones upheld the Death with Dignity Act. In September 2002, Attorney General Ashcroft filed an appeal, asking the Ninth U.S. Circuit Court of Appeals to overturn the District Court's ruling. At this time, Oregon's law remains in effect.

Requirements

The Death with Dignity Act allows terminally ill Oregon residents to obtain and use prescriptions from their physicians for self-administered, lethal medications. Under the Act, ending one's life in accordance with the law does not constitute suicide. However, we use the term "physician-assisted suicide" because it is used in the medical literature to describe ending life through the voluntary self-administration of lethal medications prescribed by a physician for that purpose. The Death with Dignity Act legalizes PAS, but specifically prohibits euthanasia, where a physician or other person directly administers a medication to end another's life. [6]

To request a prescription for lethal medications, the Death with Dignity Act requires that a patient must be:

- An adult (18 years of age or older),
- A resident of Oregon,
- Capable (defined as able to make and communicate health care decisions),
- Diagnosed with a terminal illness that will lead to death within six months.

Patients meeting these requirements are eligible to request a prescription for lethal medication from a licensed Oregon physician. To receive a prescription for lethal medication, the following steps must be fulfilled:

- The patient must make two oral requests to his or her physician, separated by at least 15 days.
- The patient must provide a written statement to his or her physician, signed in the presence of two witnesses.

- The prescribing physician and a consulting physician must confirm the diagnosis and prognosis.
- The prescribing physician and a consulting physician must determine whether the patient is capable.
- If either physician believes the patient's judgment is impaired by a psychiatric or psychological disorder, the patient must be referred for a psychological examination.
- The prescribing physician must inform the patient of feasible alternatives to assisted suicide including comfort care, hospice care, and pain control.
- The prescribing physician must request, but may not require, the patient to notify his or her next-of-kin of the prescription request.

To comply with the law, physicians must report to the Department of Human Services (DHS) all prescriptions for lethal medications [7]. Reporting is not required if patients begin the request process but never receive a prescription. In the summer of 1999, the Oregon legislature added a requirement that pharmacists must be informed of the prescribed medication's ultimate use. Physicians and patients who adhere to the requirements of the Act are protected from criminal prosecution, and the choice of legal physician-assisted suicide cannot affect the status of a patient's health or life insurance policies. Physicians and health care systems are under no obligation to participate in the Death with Dignity Act [6].

METHODS

The Reporting System

DHS is required by the Act to develop and maintain a reporting system for monitoring and collecting information on PAS [6]. To fulfill this mandate, DHS uses a system involving physician and pharmacist compliance reports, death certificate reviews, and follow-up interviews [7].

When a prescription for lethal medication is written, the physician must submit to DHS information that documents compliance with the law. We review all physician reports and contact physicians regarding missing or discrepant data. DHS Vital Records files are searched periodically for death certificates that correspond to physician reports. These death certificates allow us to confirm patients' deaths, and provide patient demographic data (e.g., age, place of residence, level of education).

In addition, using our authority to conduct special studies of morbidity and mortality [8], DHS has conducted telephone interviews with prescribing physicians after receipt of the patients' death certificates. Each physician was asked to confirm whether the patient took the lethal medications. If the patient had taken the medications, we asked physicians for information that was not available from physician reports or death certificates—including insurance status and enrollment in hospice. We asked why the patient requested a prescription, specifically exploring concerns about the financial impact of the illness, loss of autonomy, decreasing ability to participate in activities that make life enjoyable, being a burden, loss of control of bodily functions, uncontrollable pain, and loss of dignity. We collected information on the time to unconsciousness and death, and asked about any adverse reactions. Because

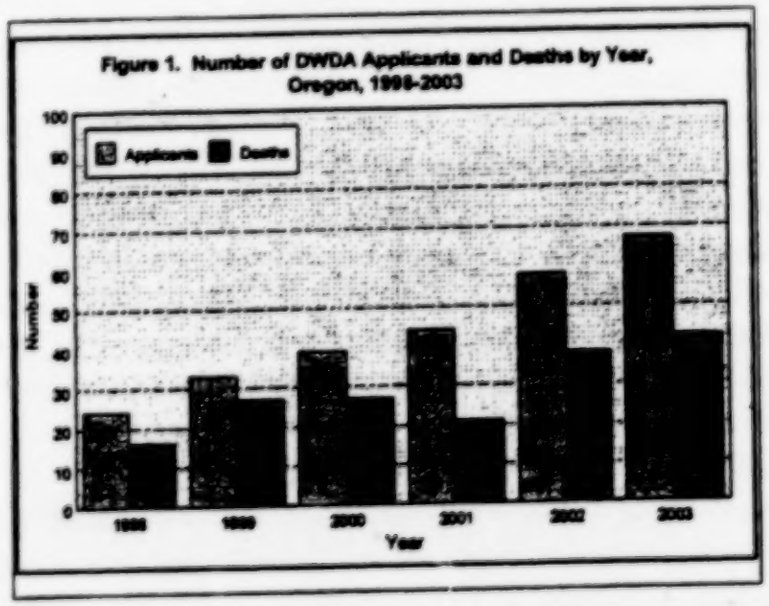
physicians are not legally required to be present when a patient ingests the medication, not all have information about what happened when the patient ingested the medication. If the prescribing physician was not present, we accepted information they had based on discussions with family members, friends or other health professionals who attended the patients' deaths. We do not interview or collect any information from patients prior to their death. Reporting forms and the physician questionnaire are available at http://www.dhs.state.or.us/publichealth/chs/pas/pasforms.cfm.

Data Analyses

We classified patients by year of participation based on when they ingested the legally-prescribed lethal medication. Using demographic information from 1997-2002 Oregon death certificates (the most recent years for which complete data are available), we compared patients who used legal PAS with other Oregonians who died from the same diseases. Demographic- and disease-specific PAS rates were computed using the number of deaths from the same causes as the denominator. The overall PAS rates by year were computed using the total number of resident deaths. Annual rates were calculated using numerator and denominator data from the same year, except for 2003 where the number of resident deaths from 2002 was used as the denominator.

RESULTS

Both the number of prescriptions written and the number of Oregonians using PAS have increased over the six years that PAS has been legal in Oregon. In 2003, 42 physicians wrote 67 prescriptions for lethal doses of medication. The number of prescriptions written has increased over the six years since legalization: 58 prescriptions were written in 2002, 44 in 2001, 39 in 2000, 33 in 1999 and 24 in 1998. Thirty-nine of the 2003 prescription recipients died after ingesting the medication. Of the 28 recipients who did not ingest the prescribed medication in 2003, 18 died from their illnesses, and 10 were alive on December 31, 2003. In addition, two patients who received prescriptions during 2002 and another who received a prescription in 2001 died in 2003, after ingesting their medication, giving a total of 42 PAS deaths during 2003 (*Figure 1*). Thirty different physicians wrote the 42 prescriptions for lethal medication.



BEST AVAILABLE COPY

The number of patients ingesting lethal medication has increased over the six years since legalization. The 42 PAS deaths in 2003 compare to 38 in 2002, 21 in 2001, 27 in 2000, 27 in 1999, and 16 in 1998. The 42 patients who ingested lethal medications in 2003 represent an estimated 14/10,000 total deaths compared with 12.2 in 2002, 7.0 in 2001, 9.1 in 2000, 9.2 in 1999, and 5.5 in 1998.

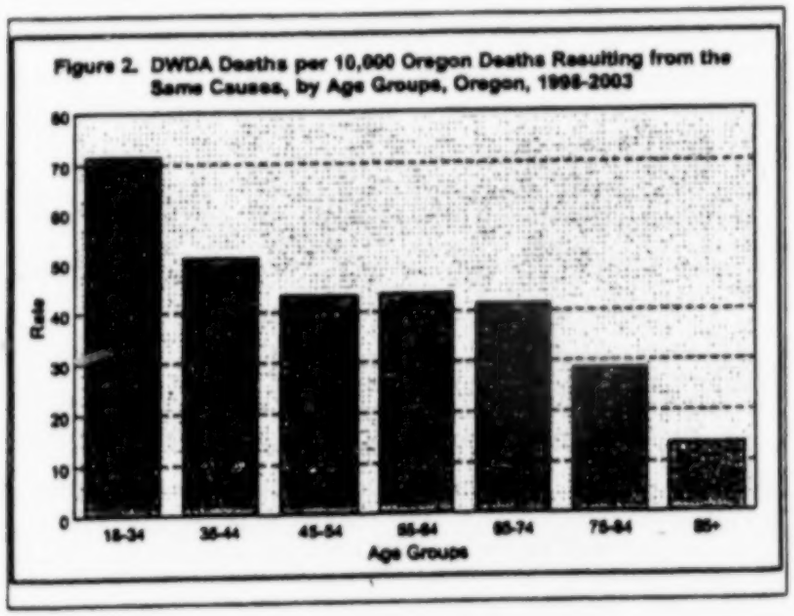
The percentage of patients referred to a specialist for psychological evaluation has declined, falling from 31 percent in 1998 to five percent in 2003.

Patient Characteristics

Oregonians using PAS during 2003 differed from those of previous years in several ways. They were more apt to be older (their median age was 73 compared to 69 for those using PAS in preceding years); they were more apt to have at least a baccalaureate degree (48% did so compared to 38% of their predecessors); and a greater proportion of patients resided in Multnomah, Clackamas, and Washington counties (45% vs. 37%). However, these figures are based on relatively few events and do not represent statistically significant differences (Table 1).

Although year-to-year variations occur, certain demographic patterns have become evident over the past six years. Males and females were equally likely to take advantage of the DWDA, but terminally ill younger persons were significantly more likely to turn to PAS than their older counterparts; 18- to 34-year-olds were 5.3 times more likely to use PAS than were those 85 or older (Table 2 and *Figure 2*). Asian Oregonians were about three times as likely to use PAS as were white Oregonians. Divorced and never-married persons were about two times more likely to use PAS

than married and widowed residents. A higher level of education was strongly associated with the use of PAS; Oregonians with a baccalaureate degree or higher were 7.6 times more likely to use PAS than those without a high school diploma. By region, residents living east of the Cascade Range were less than half as likely to use PAS as those living in western Oregon.



The type of terminal illness is a strong predictor of the likelihood of a patient using PAS (Table 3). The rates of DWDA deaths to non-PAS deaths resulting from the same causes were high for three conditions: amyotrophic lateral sclerosis (ALS) (249.0 per 10,000), HIV/AIDS (171.4), and malignant neoplasms (37.6). Among the causes associated with at least three deaths, the lowest rate (9.7) was for patients with chronic lower respiratory diseases (CLRD), such as emphysema. Persons with ALS (Lou Gehrig's disease) were more than 25 times as likely to use PAS as were those with CLRD.

During 2003, most patients died at home, but two died at assisted living residences while another died in a physician's office. All individuals had some form of health insurance (Table 4). As in previous years, most (93%) of the patients who used PAS in 2003 were enrolled in hospice care. The median length of the patient-physician relationship was ten weeks.

Physician Characteristics

The prescribing physicians of patients who used PAS during 2003 had been in practice a median of 21.5 years (range 3-35). Their medical specialties included: internal medicine (12%), oncology (38%), family medicine (45%), and other (5%).

Prescribing physicians were present while 12 (29%) of the 42 patients ingested the lethal medications. Among the remaining 30 patients, 67% ingested the medication in the presence of another health-care provider/volunteer.

During 2003, one case involving possible non-compliance with DWDA provisions regarding witnessing of signatures was reported to the Oregon Board of Medical Examiners.

Lethal Medication

During 1998-2002, secobarbital was the lethal medication prescribed for 85 of the 129 patients (66%). During 2003, 37 patients (88%) used pentobarbital, four patients used secobarbital, and one used secobarbital/amobarbital. Since the DWDA was implemented, 52% of the PAS

patients used secobarbital, 46% used pentobarbital, and 2% used other medications (mostly secobarbital/amobarbital).

Complications

During 2003, physicians reported that three patients experienced complications: a small emesis was reported for one patient who died 20 minutes after ingestion of the lethal medication. Another patient consumed about 60% of the prescribed pentobarbital, regurgitated about one-third of the medication consumed to that point, and then drank one-half of the remaining medication, dying 20 minutes later. A third patient drank one-half of the prescribed medication and about 30 seconds later regurgitated one-third of what had been consumed, retaining only about 3 grams of the barbiturate. This patient lived for 48 hours after having ingested only about one-third of the intended dose.

One physician reported that a patient fell asleep before ingesting the entire dose of medication. The patient died 40 minutes after ingestion.

None of the patients regained consciousness after ingesting the lethal medication.

Emergency medical services were contacted by a family in one case to pronounce death but not to intervene or transport the patient.

End of Life Concerns

Physicians were asked if, based on discussions with patients, any of seven end-of-life concerns might have contributed to the patients' requests for lethal medication (Table 4). In nearly all cases, physicians reported multiple concerns contributing to the request. During 2003, one patient (2%) was reported to have one end-of-life concern,

13 (31%) had two concerns, 15 (36%) had three concerns, nine (21%) had four concerns, and four (10%) had five concerns. The most frequently reported concerns included losing autonomy (93%), a decreasing ability to participate in activities that make life enjoyable (93%), and loss of dignity (82%). (The frequency of the latter concern was assessed for the first time in 2003.)

COMMENTS

During the six years since legalization, the number of prescriptions written for physician-assisted suicide and the number of terminally ill patients taking lethal medication has increased. However, the number has remained small compared to the total number of deaths in Oregon, with about 1/7 of one percent of Oregonians dying by PAS. This proportion is consistent with numbers from a survey of Oregon physicians [9]. Overall, smaller numbers of patients appear to use PAS in Oregon compared to the Netherlands [10]. However, as detailed in previous reports [1-5], our numbers are based on a reporting system for terminally ill patients who legally receive prescriptions for lethal medications, and do not include patients and physicians who may act outside the provisions of the DWDA.

Over the last six years the rate of PAS among patients with ALS in Oregon has been substantially higher than among patients with other illnesses. This finding is consistent with other studies. In the Netherlands, where both PAS and euthanasia are openly practiced, one in five ALS patients died as a result of PAS or euthanasia [11]. A study of Oregon and Washington ALS patients found that one-third of these patients discussed wanting PAS in the last month of life [12]. It is not known with certainty why ALS

patients would be more likely to choose PAS than would other terminally ill patients. Oregon HIV/AIDS patients are also disproportionately likely to use PAS, a finding consistent with studies elsewhere [13].

Physicians have consistently reported that concerns about loss of autonomy and decreased ability to participate in activities that make life enjoyable are important motivating factors in patient requests for lethal medication across all six years. Interviews with family members during 1999 corroborated physician reports [2]. These findings were supported by a recent study of hospice nurses and social workers caring for PAS patients in Oregon [14].

The availability of PAS may have led to efforts to improve end-of-life care through other modalities. While it may be common for patients with a terminal illness to consider PAS, a request for PAS can be an opportunity for a medical provider to explore with patients their fears and wishes around end-of-life care, and to make patients aware of other options. Often once the provider has addressed a patient's concerns, he or she may choose not to pursue PAS [15]. The availability of PAS as an option in Oregon also may have spurred Oregon doctors to address other end-of-life care options more effectively. In one study, Oregon physicians reported that, since the passage of the Death with Dignity Act in 1994, they had made efforts to improve their knowledge of the use of pain medications in the terminally ill, to improve their recognition of psychiatric disorders such as depression, and to refer patients more frequently to hospice [16].

REFERENCES

1. Chin G, Hedberg K, Higginson G, Fleming D. Legalized physician-assisted suicide in Oregon—The first year's experience. N Engl J Med, 1999;340:577-83.
2. Sullivan AD, Hedberg K, Fleming D. Legalized physician-assisted suicide in Oregon—The second year. N Engl J Med, 2000;342:598-604.
3. Sullivan AD, Hedberg K, Hopkins D. Legalized physician-assisted suicide in Oregon, 1998-2000. N Engl J Med, 2001;344:605-7.
4. Hedberg K, Hopkins D, Southwick K. Legalized physician-assisted suicide in Oregon, 2001. N Engl J Med, 2002;346:450-2.
5. Hedberg K, Hopkins D, Kohn M. Five years of legal physician-assisted suicide in Oregon. N Engl J Med, 2003;348:961-4.
6. Oregon Revised Statute 127.800-127.995. Available at http://www.dhs.state.or.us/publichealth/chs/pas/ors.cfm
7. Oregon Administrative Rules 333-009-000 to 333-009-0030. Available at http://www.dhs.state.or.us/publichealth/chs/pas/oars.cfm
8. Oregon Revised Statute 432.060. http://www.leg.state.or.us/ors/432.html
9. Ganzini L, Nelson HD, Schmidt TA, et al. Physicians' experiences with the Oregon Death with Dignity Act. N Engl J Med, 2000;342:557-63.

10. Willems DL, Daniels ER, van der Wal G, et al. Attitudes and practices concerning the end of life: A comparison between physicians from the United States and from The Netherlands. Arch Intern Med, 2000;160:63-8.

11. Vledink JH, Wokke JHJ, Van Der Wal G, et al. Euthanasia and physicians-assisted suicide among patients with amyotrophic lateral sclerosis in the Netherlands. N Engl J Med, 2002;346:1638-44.

12. Ganzini L, Silveira MJ, Johnston WS. Predictors and correlates of interest in assisted suicide in the final month of life among ALS patients in Oregon and Washington. J Pain Symptom Manage, 2002;3:312-7.

13. Bosshard G, Ulrich E, Bar W. 748 Cases of suicide assisted by a Swiss right-to-die organization. Swiss Med Wkly, 2003;133:310-317.

14. Ganzini L, Harvath TA, Jackson A, et al. Experiences of Oregon nurses and social workers with hospice patients who requested assistance with suicide. N Engl J Med, 2002;347:582-8.

15. Bascom PB, Tolle SW. Responding to requests for physician-assisted suicide: "these are uncharted waters for both of us . . .". JAMA, 2002;288:91-8.

14. Ganzini L, Nelson HD, Lee MA, et al. Oregon physicians' attitudes about and experiences with end-of-life care since the passage of the Oregon Death with Dignity Act. JAMA 2001;285:2363-9.

Table 1. Demographic characteristics of 171 DWDA patients who died after ingesting a lethal dose of medication, by year, Oregon, 1998-2003.

Characteristics	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
Sex			
Male (%)	19 (45)	71 (55)	90 (53)
Female (%)	23 (55)	58 (45)	81 (47)
Age			
18-34 (%)	0 (0)	2 (2)	2 (1)
35-44 (%)	2 (5)	3 (2)	5 (3)
45-54 (%)	4 (10)	10 (8)	14 (8)
55-64 (%)	8 (19)	21 (16)	29 (17)
65-74 (%)	9 (21)	46 (36)	55 (32)
75-84 (%)	14 (33)	37 (29)	51 (30)
85+ (%)	5 (12)	10 (8)	15 (9)
Median years (Range)	73 (40-93)	69 (25-94)	70 (25-94)
Race			
White (%)	41 (98)	125 (97)	166 (97)
Asian (%)	1 (2)	4 (3)	5 (3)
Other (%)	0	0	0
Marital status			
Married (%)	15 (36)	60 (47)	75 (44)
Widowed (%)	12 (29)	29 (23)	41 (24)
Divorced (%)	10 (24)	32 (25)	42 (25)
Never married (%)	5 (12)	8 (6)	13 (8)
Education			
Less than high school (%)	2 (5)	14 (11)	16 (9)
HS graduate (%)	8 (19)	43 (33)	51 (30)

Characteristics (Cont'd)	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
Education (Cont'd)			
Some college (%)	12 (29)	23 (18)	35 (21)
Baccalaureate or higher (%)	20 (48)	49 (38)	69 (40)
Residence			
Metro counties (%)**	19 (45)	48 (37)	67 (39)
Coastal counties (%)***	3 (7)	11 (9)	14 (8)
Other W. counties (%)	19 (45)	60 (47)	79 (46)
E. of the Cascades (%)	1 (2)	10 (8)	11 (6)
Underlying illness			
Malignant neoplasms (%)	35 (83)	100 (78)	135 (79)
Lung and bronchus (%)	9 (21)	24 (19)	33 (19)
Breast (%)	6 (14)	10 (8)	16 (9)
Pancreas (%)	4 (10)	12 (9)	16 (9)
Colon (%)	3 (7)	7 (5)	10 (6)
Other (%)	13 (31)	47 (36)	60 (35)
Amyotrophic lateral sclerosis (%)	3 (7)	10 (8)	13 (8)
Chronic lower respiratory dis. (%)	1 (2)	8 (6)	9 (5)
HIV/AIDS (%)	2 (5)	1 (1)	3 (2)
Illnesses listed below (%)#	1 (1)	10 (8)	11 (6)

* Unknowns are excluded when calculating percentages.

** Clackamas, Multnomah, and Washington counties.

*** Excluding Douglas and Lane counties.

Includes aortic stenosis, congestive heart failure, diabetes mellitus with renal complications, gastrointestinal stromal tumor, myelodysplastic syndrome, pulmonary disease with fibrosis, scleroderma, and Shy-Drager syndrome.

Table 2. Demographic characteristics of 171 patients who died during 1998-2003 after ingesting a lethal dose of medication compared with 53,544 Oregonians dying from the same underlying diseases.

Characteristics	PAS patients 1998-2003 (N = 171)*	Oregon deaths, same diseases (N = 53,544)*	DWDA deaths per 10,000 Oregon deaths	Rate ratio (95% CI**)
Sex				
Male (%)	90 (53)	26,972 (50)	33.4	1.1 (0.8-1.5)
Female (%)	81 (47)	26,572 (50)	30.5	1.0
Age				
18-34 (%)	2 (1)	281 (1)	71.2	5.3 (1.2-22.9)#
35-44 (%)	5 (3)	985 (2)	50.8	3.8 (1.4-10.3)
45-54 (%)	14 (8)	3,235 (6)	43.3	3.2 (1.6-6.6)
55-64 (%)	29 (17)	6,674 (13)	43.5	3.2 (1.7-6.0)
65-74 (%)	55 (32)	13,309 (25)	41.3	3.1 (1.7-5.4)
75-84 (%)	51 (30)	17,969 (34)	28.4	2.1 (1.2-3.7)
85+ (%)	15 (9)	11,091 (21)	13.5	1.0
Median years	70	76		
Race				
White (%)	166 (97)	52,100 (97)	31.9	1.0
Asian (%)	5 (3)	535 (1)	93.5	2.9 (1.2-7.1)+
Other (%)	0	898 (2)	0	0
Unknown	*0*	*11*		

* Unknowns are excluded when calculating percentages.

** Confidence interval.

The ratio is statistically significant according to the chi-square test for trend.

+ The ratio is statistically significant according to the chi-square test.

Characteristics	PAS patients 1998-2003 (N = 171)*	Oregon deaths, same diseases (N = 53,544)*	DWDA deaths per 10,000 Oregon deaths	Rate ratio (95% CI**)
Marital status				
Married (%)	75 (44)	26,003 (49)	28.8	1.0
Widowed (%)	41 (24)	17,742 (33)	23.1	0.8 (0.6-1.2)
Divorced (%)	42 (25)	7,530 (14)	55.8	1.9 (1.3-2.8)+
Never Married (%)	13 (8)	2,168 (4)	60.0	2.1 (1.2-3.7)+
Unknown	*0*	*101*		
Education				
Less than high school (%)	16 (9)	12,954 (25)	12.4	1.0
HS graduate (%)	51 (30)	22,855 (43)	22.3	1.8 (1.0-3.2)
Some college (%)	35 (21)	9,598 (18)	36.5	3.0 (1.6-5.3)
Baccalaureate or higher (%)	69 (40)	7,392 (14)	93.3	7.6 (4.4-13.0)#
Unknown	*0*	*745*		
Residence				
Metro counties (%)	67 (39)	19,333 (36)	34.7	1.0
Coastal counties (%)	14 (8)	4,374 (8)	32.0	0.9 (0.5-1.6)
Other W. counties (%)	79 (46)	22,259 (42)	35.5	1.0 (0.7-1.4)
E. of the Cascades (%)	11 (6)	7,578 (14)	14.5	0.4 (0.2-0.8)+

(*Relevant footnotes are listed on the previous page.*)

Table 3. Underlying illnesses of 171 patients who died during 1998-2003 after ingesting a lethal dose of medication compared with 53,544 Oregonians dying from the same underlying diseases.

Underlying illnesses	PAS patients 1998-2003 (N=171)	Oregon deaths, same diseases (N=53,544)	DWDA deaths per 10,000 Oregon deaths	Rate ratio (95% CI*)
Malignant neoplasms (%)	135 (79)	35,906 (67)	37.6	3.9(2.0-7.6)+
Lung and bronchus (%)	33 (19)	12,037 (23)	27.4	2.8(1.4-5.9)+
Breast (%)	16 (9)	3,037 (6)	52.7	5.4(2.4-12.3)+
Pancreas (%)	16 (9)	2,190 (4)	73.1	7.5(3.3-17.1)+
Colon (%)	10 (6)	3,171 (6)	31.5	3.3(1.3-8.0)+
Prostate (%)	9 (5)	2,670 (5)	33.7	3.5(1.4-8.8)+
Ovary (%)	9 (5)	1,178 (2)	76.4	7.9(3.1-19.9)+
Skin (%)	6 (4)	522 (1)	114.9	11.9(4.2-33.2)+
Other (%)	36 (21)	11,101 (21)	32.4	3.4(1.6-7.0)+
Amyotrophic lateral sclerosis (%)	13 (8)	522 (1)	249.0	25.7(11.1-59.9)+
Chronic lower respiratory dis. (%)	9 (5)	9,300 (17)	9.7	1.0
HIV/AIDS (%)	3 (2)	175 (<1)	171.4	17.7(4.8-64.9)+
Illnesses listed below (%)**	11 (6)	7,641 (14)	14.4	1.5(0.6-3.6)

* Confidence interval.

** Includes aortic stenosis, congestive heart failure, diabetes mellitus with renal complications, gastrointestinal stromal tumor, myelodysplastic syndrome, pulmonary disease with fibrosis, scleroderma, and Shy-Drager syndrome.

+ The ratio is statistically significant according to the chi-square test.

Table 4. Death with Dignity Act participant end of life care and DWDA utilization. Based on physician interviews for 171 patients who died after ingesting a lethal dose of medication - Oregon, 1998-2003.

Characteristics	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
End of Life Care			
Hospice			
Enrolled (%)	39 (93)	106 (83)	145 (86)
Declined by patient (%)	3 (7)	21 (17)	24 (14)
Unknown	–	*2*	*2*
Insurance			
Private (%)	22 (52)	80 (63)	102 (61)
Medicare or Medicaid (%)	20 (48)	44 (35)	64 (38)
None (%)	–	2 (2)	2 (1)
Unknown	–	*3*	*3*
End of Life Concerns+			
Losing autonomy (%)	39 (93)	106 (85)	145 (87)
Less able to engage in activities making life enjoyable (%)	39 (93)	99 (79)	138 (83)
Loss of dignity (%)++	31 (82)	–	31 (82)
Losing control of bodily functions (%)	24 (57)	73 (58)	97 (58)

* Unknowns are excluded when calculating percentages unless otherwise noted.

** Patients discussing concern about inadequate pain control with their physicians were not necessarily experiencing pain.

\+ Affirmative answers only ("Don't know" included in negative answers). Available for 17 patients in 2001.

++ First asked in 2003.

Characteristics (Cont'd)	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
End of Life Concerns+ **(Cont'd)**			
Burden on family, friends/ caregivers (%)	16 (38)	44 (35)	60 (36)
Inadequate pain control (%)**	9 (21)	28 (22)	37 (22)
Financial implications of treatment (%)	1 (2)	3 (2)	4 (2)
PAS Process			
Referred for psychiatric evaluation (%)	2 (5)	28 (23)	30 (18)
Patient died at Home (patient, family or friend (%)	39 (93)	121 (94)	160 (94)
Long term care, assisted living or foster care facility (%)	2 (5)	6 (5)	8 (5)
Hospital (%)	0	1 (1)	1 (1)
Other (%)	1 (2)	1 (1)	2 (1)
Lethal Medication			
Secobarbital (%)	4 (10)	85 (66)	89 (52)
Pentobarbital (%)	37 (88)	41 (32)	78 (46)
Secobarbital/ amobarbital (%)	1 (2)	2 (2)	3 (2)
Other (%)	0	1 (1)	1 (1)

(Relevant footnotes are listed on the previous page.)

Characteristics (Cont'd)	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
Health-care provider present when medication ingested#			
Prescribing physician (%)	12 (29)	22 (39)	34 (34)
Other provider, prescribing physician not present (%)	20 (48)	29 (51)	49 (49)
No provider (%)	10 (24)	6 (11)	16 (16)
Unknown	*0*	*2*	*2*
Regurgitation/seizures after medication ingested			
Regurgitated (%)	3 (7)	4 (3)	7 (4)
Seizures (%)	0	0	0
Neither (%)	39 (93)	121 (97)	160 (96)
Unknown	*0*	*4*	*4*
Emergency Medical Services			
Called for intervention after lethal medication ingested (%)***	0	0	0
Not called after lethal medication ingested (%)	42 (100)	126 (100)	168 (100)
Unknown	*0*	*3*	*3*

* Unknowns are excluded when calculating percentages unless otherwise noted.

*** Excludes calls to pronounce death.

The data shown are for 2001-2003. Information about the presence of a health care provider/volunteer, in absence of the prescribing physician, was first collected in 2001. Attendance by the prescribing physician has been recorded since 1998. During 1998-2002 the prescribing physician was present when 47% of the patients ingested the lethal medication.

Characteristics (Cont'd)	2003 (N = 42)*	1998-2002 (N = 129)*	Total (N = 171)*
Timing of PAS Event			
Duration (weeks) of patient-physician relationship			
Median	10	13	13
Range	0-405	0-851	0-851
Duration (days) between 1st request and death			
Median	36	43	39
Range	16-737	15-466	15-737
Minutes between ingestion and unconsciousness			
Median	4	5	5
Range	1-20	1-38	1-38
Unknown	*2*	*18*	*20*
Minutes between ingestion death			
Median	20	30	25
Range (minutes - hours)	5m-48h	4m-37h	4m-48h
Unknown	*1*	*12*	*13*

(Relevant footnote is listed on the previous page.)

[LETTERHEAD]

HELLEREHRMAN
ATTORNEYS

Hilary E. Ware
hware@hewm.com
Direct (415) 772-6459
Main (415) 772-6000
Fax (415) 772-6268

March 19, 2003

Via Hand Delivery

[Stamp]
RECEIVED
OFFICE OF THE CLERK
U.S. COURT OF APPEALS
PUBLIC INFORMATION UNIT
03 MAR 19 PM 12:34
FILED _____
DOCKETED _____
DATE INITIAL

Office of the Clerk
United States Court of Appeals for the
Ninth Circuit
P.O. Box 193939
San Francisco, CA 94119-3939

Re: *State of Oregon et al., v. Ashcroft*
Case No. 02-35587

Dear Sir or Madam:

Pursuant to Rule 28(j) of the Federal Rules of Appellate Procedure, the Patient Plaintiffs-Appellees in the above-mentioned case wish to request the Court's permission to cite a significant supplemental authority that has recently been released. On March 6, 2003, the *New England Journal of Medicine* published "Five Years of Legal Physician-Assisted Suicide in Oregon," an examination of data from the fifth year of the Oregon Death With Dignity Act ("ODWDA"). The Patient Plaintiffs-Appellees cited and discussed the data contained in the reports from the first four years of the ODWDA in their Brief at pages 13-14; the report from the fifth year should also be considered in that context.

A copy of this report is enclosed with this request, and is also available at www.http://content.nejm.org/cgi/content/full/348/10/961. Thank you for your consideration of this request.

Very truly yours,

/s/ HILARY E. WARE
Hilary E. Ware

cc: All Counsel of Record
Enclosures

[Letterhead bottom:]

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Volume 348:961-964
March 6, 2003
Number 10

Five Years of Legal Physician-Assisted Suicide in Oregon

To the Editor: Physician-assisted suicide for terminally ill residents of Oregon has been legal since October 1997.[1] Although it has been challenged several times in court and by a referendum, the Oregon Death with Dignity Act remains in effect at this time. As the state public health agency with the mandate to monitor the use of physician-assisted suicide, we require physicians to file reports on patients for whom a prescription for a lethal medication is written. We analyzed data from these report forms, interviews with physicians, and death certificates. As part of follow-up to previous reports,[2,3,4,5] we characterized patients who died in 2002 after ingesting legally prescribed lethal medications and evaluated trends in the numbers of prescriptions written and in the numbers and characteristics of the patients who ingested lethal medications during the five years since implementation. We compared all patients who chose physician-assisted suicide during the first five years with other residents of Oregon who died of the same underlying diseases.

During 2002, 33 physicians wrote prescriptions for lethal medications for 58 Oregon residents. The number of prescriptions written has increased over the five-year period since implementation (24 in 1998, 33 in 1999, 39 in 2000, 44 in 2001, and 58 in 2002; P for trend <0.001 by the chi-square test). During 2002, 38 persons died from ingesting the prescribed lethal medications, and 8 who received prescriptions for lethal medications are still alive (6 of them received prescriptions in 2002, and 2 of them received prescriptions in 2001). The number of patients who died from ingesting prescribed lethal medications has increased since 1998 (16 in 1998, 27 in 1999, 27 in 2000, 21 in 2001, and 38 in 2002; P for trend <0.02 by the chi-square test).

In the five years during which the law has been in effect, a total of 129 people used physician-assisted suicide in Oregon. This corresponds to a rate of 8.8 per 10,000 deaths from any cause in Oregon. *Table 1* shows the characteristics of patients who have ingested prescribed lethal medications since legalization. Among Oregon residents who died of the same underlying diseases as those who chose physician-assisted suicide, rates of use of physician-assisted suicide decreased with age and were higher among those who had been divorced and among those with higher levels of educational attainment. The rate of use of physician-assisted suicide was significantly higher among those who had amyotrophic lateral sclerosis (374.5 per 10,000) or cancer (61.0 per 10,000) than among those who had other terminal illnesses. Men and women were equally likely to choose physician-assisted suicide. Although the majority of patients were non-Hispanic whites, the rate of use of physician-assisted suicide among terminally ill Asian Americans was higher (91.7 per 10,000) (*Table 1*).

Despite increases, the number of terminally ill Oregon residents using physician-assisted suicide remains small relative to the overall number of deaths.

Katrina Hedberg, M.D., M.P.H.
David Hopkins, M.S.
Melvin Kohn, M.D., M.P.H.
Oregon Public Health Services
Portland, OR 97232
katrina.hedberg@state.or.us

References

1. Oregon's Death with Dignity Act. Oregon revised statute 127.800-127.995. Portland: Oregon Public Health Services, 2003. (Accessed February 14, 2003, at http://www.healthoregon.org/chs/pas/pas.cfm.)
2. Chin AE, Hedberg K, Higginson GK, Fleming DW. Legalized physician-assisted suicide in Oregon--the first year's experience. N Engl J Med 1999;340:577-583. [Abstract/Full Text]
3. Sullivan AD, Hedberg K, Fleming DW. Legalized physician-assisted suicide in Oregon--the second year. N Engl J Med 2000;342:598-604. [Abstract/Full Text]
4. Sullivan AD, Hedberg K, Hopkins D. Legalized physician-assisted suicide in Oregon, 1998-2000. N Engl J Med 2001;344:605-607. [Full Text]
5. Hedberg K, Hopkins D, Southwick K. Legalized physician-assisted suicide in Oregon, 2001. N Engl J Med 2002;346:450-452. [Full Text]

Table 1. Characteristics of Patients in Oregon Who Died after Ingesting Legally Prescribed Lethal Medication and of All Patients Who Died from the Same Underlying Diseases.

June 5, 1998

The Honorable Henry J. Hyde
Chairman
Committee on the Judiciary
U.S. House of Representative
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your request concerning the question whether the Department of Justice, through the Drug Enforcement Administration ("DEA"), may invoke the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971, to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances. The issue has arisen in the context of Oregon's "Death with Dignity Act," Oreg. Rev. Stat. §§ 127.800-127.995, which permits physicians to assist competent, terminally ill patients in ending their lives in compliance with certain detailed procedures. The Department has reviewed the issue thoroughly and has concluded that adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.

The Oregon Act was approved by Oregon voters on November 8, 1994, and went in to effect on October 27, 1997. The Act provides for a detailed procedure by which a mentally competent, terminally ill patient may request to end his or her life "in a humane and dignified manner." O.R.S. § 127.805. The procedure requires, for example, that the patient's competence and the voluntariness of the request be documented in writing and confirmed by two

witnesses, *see id.* § 127.810(1), that the patient's illness and competence and the voluntariness of the request by [*sic*] confirmed by a second physician, *see id.* § 127.820, and that the physician and patient observe certain waiting periods, *see id.* §§ 127.840, 127.850. Once a request has been properly documented and the requisite waiting periods have expired, the patient's attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life. As a matter of state law, physicians acting in accordance with the Oregon Act are immune from liability as well as any adverse disciplinary action for having rendered such assistance.

Prior to the Oregon Act's taking effect last year, you wrote to DEA Administrator Thomas Constantine seeking the DEA's view as to whether delivering, distributing, dispensing, prescribing, or administering a controlled substance with the intent of assisting in a suicide would violate the CSA notwithstanding a state law such as the Oregon Act. In response, Administrator Constantine explained that "physician-assisted suicide would be a new and different application of the CSA," and that the determination whether to pursue adverse action under the CSA would first require "a medico-legal investigation" involving "state and local law enforcement agencies and prosecutors." He also stated, however, that "the activities that you described in your letter to us would be, in our opinion, a violation of the CSA." Subsequently, many other Members of Congress have sent letters urging that I support the DEA's conclusions and enforce federal laws and regulations accordingly. I have received other correspondence supporting a contrary conclusion.

The Department has conducted a thorough and careful review of the issue of whether the CSA authorizes adverse

action against a physician who prescribes a controlled substance to assist in a suicide in compliance with Oregon law.

The CSA is a complex regulatory scheme that controls the authorized distribution of scheduled drugs. Physicians, for example, are authorized to prescribe and distribute scheduled drugs only pursuant to their registration with the DEA, and the unauthorized distribution of drugs is generally subject to criminal and administrative action. The relevant provisions of the CSA provide criminal penalties for physicians who dispense controlled substances beyond "the course of professional practice," 21 U.S.C. 802 (21), *see id.* § 841 (b), and provide for revocation of the DEA drug registrations of physicians who have engaged either in such criminal conduct or in other "conduct which may threaten the public health and safety," *id.* § 823 (f). Because these terms are not further defined by the statute, we must look to the purpose of the CSA to understand their scope.

The CSA was intended to keep legally available controlled substances within lawful channels of distribution and use. *See* S. Rep. No. 91-613, at 3 (1969). It sought to prevent both the trafficking in these substances for unauthorized purposes and drug abuse. The particular drug abuse that Congress intended to prevent was that deriving from the drug's "stimulant, depressant, or hallucinogenic effect on the central nervous system," 21 U.S.C. § 811 (f).

There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice. Indeed, the CSA is essentially silent with regard to regu-

lating the practice of medicine that involves legally available drugs (except for certain specific regulations dealing with the treatment of addicts, see 42 U.S.C. § 257a; 21 C.F.R. § 291.505).

Even more fundamentally, there is no evidence that Congress, in the CSA, intended to assign DEA the novel role of resolving the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide," *Washington v. Glucksberg*, 117 S. Ct. 2258, 2275 (1997), simply because that procedure involves the use of controlled substances. If Congress had assigned DEA this role under the CSA, it would ultimately be DEA's task to determine whether assistance in the commission of a suicide, in compliance with a state law specifically permitting and regulating suck [*sic*] assistance, nevertheless falls outside the public interest. These questions, however, are not susceptible of scientific or factual resolution, but rather are fundamental questions of morality and public policy. Such a mission falls well beyond the purpose of the CSA.

The state of Oregon has reached the considered judgment that physician-assisted suicide should be authorized under narrow conditions and in compliance with certain detailed procedures. Under these circumstances, we have concluded that the CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law. We emphasize that out [*sic*] conclusion is limited to these particular circumstances. Adverse action under the CSA may well be warranted in other circumstances: for example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions, or where a physician fails to comply with state procedures in doing so. However, the federal government's pursuit of adverse

actions against Oregon physicians who fully comply with that state's Death with Dignity Act would be beyond the purpose of the CSA.

Finally, notwithstanding our interpretation of the CSA as it applies to the Oregon Act, it is important to underscore that the President continues to maintain his longstanding position against assisted suicide and any Federal support for that procedure. This position was recently codified when he signed the Assisted Suicide Funding Restriction Act last year. While states ordinarily have primary responsibility for regulating physicians, the President and the Administration nonetheless remain open to working with you and other interested members of Congress on this complex but extremely important issue.

Sincerely,

Janet Reno

[LETTERHEAD]

[Round Seal]

DEPARTMENT OF JUSTICE

1162 Court Street NE
Justice Building
Salem, Oregon 97301-4096

Telephone (503) 378-4400
TTY: (503) 378-5938

February 2, 2001

Honorable John Ashcroft
Attorney General of the United States
United States Department of Justice
Room 5111
Tenth and Constitution Avenues, NW
Washington, DC 20530

Dear Attorney General Ashcroft:

I want to extend warmest congratulations on your confirmation and accession to office as Attorney General of the United States. Given your former service as Attorney General of Missouri and your active role in the National Association of Attorneys General, I know you assume your new office with a strong understanding of the many-faceted relationship between state and territorial Attorneys General and the United States Department of Justice. I look forward to joining my counterparts in the other states and territories in making that relationship with your administration as cordial and productive as possible.

In your new service you may soon be addressing an issue of major significance to my state: whether to support a reversal of the United States Department of Justice's present interpretation of the Federal Controlled Substances Act (CSA) in relation to physician prescription of controlled substances in circumstances that comply with Oregon's physician-assisted suicide law (Ballot Measure 16). As you may know, the people of Oregon adopted that law by initiative and later rejected a measure, referred to them by the Oregon Legislative Assembly, repealing Ballot Measure 16.

In 1997 the United States Department of Justice concluded that the CSA does not authorize the Drug Enforcement Administration to revoke a physician's federal controlled substances registration on the ground the physician has prescribed controlled substances in conformity with Ballot Measure 16. That conclusion followed a meeting with the Department of Justice at which my representative, joined by a representative of Governor Kitzhaber, had the opportunity to present our legal analysis supporting the interpretation of the CSA the Department of Justice later adopted.

Some have speculated that the previous interpretation of the CSA may be reexamined and possibly reversed. Such reversal would presumably subject Oregon physicians to DEA revocation of their controlled substances registration, and possible criminal prosecution, if they prescribe controlled substances in compliance with Ballot Measure 16.

If the current interpretation of the CSA in relation to Ballot Measure 16 is to be reexamined, Governor Kitzhaber and I request a renewed opportunity for our representatives to meet with yours to discuss my office's

analysis of the CSA in relation to Ballot Measure 16. We make that request, of course, from a desire to avoid a CSA interpretation we believe would be inconsistent with Congress' intent in enacting the CSA, and a resulting course of CSA enforcement we believe would therefore be unlawful.

Again, please accept sincerest congratulations on your assuming an office of great importance in the life of our nation.

Respectfully yours,

/s/ HARDY MYERS
HARDY MYERS
Attorney General

cc: Governor John Kitzhaber
United States Senator Ron Wyden
United States Senator Gordon Smith

[LETTERHEAD]

[Round Seal] U.S. Department of Justice
Office of Intergovernmental Affairs

Office of the Director *Washington, D.C. 20530*
April 17, 2001

The Honorable Hardy Myers
Attorney General
State of Oregon
Salem, OR 97301-4096

Dear Attorney General Hardy:

Thank you for your letter of February 2, 2001, to the Attorney General congratulating him on his confirmation. I am sorry for the delay in responding. In your letter you expressed concern that the Department may revisit its existing interpretation of the Controlled Substances Act (CSA) as it applies to physicians prescribing a controlled substance to assist in a suicide. The Attorney General has asked me to respond on his behalf.

I am aware of no pending legislation in Congress that would prompt a review of the Department's interpretation of the CSA as it relates to physician-assisted suicide. Should such a review be commenced in the future, we would be happy to include your views in that review.

On behalf of the Attorney General, I thank you for writing and expressing your views on this important matter.

Sincerely,

/s/ LORI SHARPE
Lori Sharpe
Director and Advisor
to the Attorney General